



STATE OF IOWA

TERRY E. BRANSTAD
GOVERNOR

KIM REYNOLDS
LT. GOVERNOR

OFFICE OF DRUG CONTROL POLICY
STEVEN F. LUKAN, DIRECTOR

Cannabis-Based Medicines vs. “Medical Marijuana”

The Governor’s Office of Drug Control Policy (ODCP) supports the development of safe, tested and effective science-based medicines that do not compromise public safety in Iowa. ODCP encourages research-based medicines standardized and approved for measured use with physician and pharmacy oversight to treat valid medical needs, similar to other medicines currently being studied or already authorized by the FDA.

ODCP recently contacted the U.S. Food and Drug Administration and GW Pharmaceuticals for more information on research that could lead to additional development of, and broader access to, cannabis-based treatments for appropriate medical needs. ODCP has also spoken with the Director of Pediatric Epilepsy in the Division of Pediatric Neurology at University of Iowa Hospitals and Clinics about her efforts to help Iowa families access experimental medicines being researched under the auspices of the FDA.

The following brief updates recap recent conversations between ODCP and some of those involved in developing or accessing cannabis-based medicines.

- ❖ GW Pharmaceuticals is in final clinical trials in the U.S. with a cannabis-based mouth spray product (Sativex), to treat cancer pain and possibly MS spasticity. In early 2014, GW also started U.S. testing of a cannabis-based liquid formulation product (Epidiolex), to treat adolescent Dravet syndrome patients with severe seizures.
- ❖ The FDA has two primary pathways for patients to access unapproved drugs under study: (1) clinical trials; and (2) Investigational New Drug programs. Sativex is nearing the end of its clinical trials phases, and will then be considered for FDA approval. Epidiolex was designated an “orphan drug” late in 2013, and is available on a limited basis through an expanded access IND program in which physicians may apply on behalf of eligible patients. Additional patient access points for Epidiolex are under active consideration.
- ❖ Sativex is equal parts tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is the psychoactive element in cannabis that creates mind-altering experiences that can lead to abuse, impairment or addiction. CBD does not get you high. Epidiolex is purified CBD mixed with an artificial sweetener to create a syrup-like product.

- ❖ By contrast, much of the “medical marijuana” sold in states that have voted to permit it involves crude marijuana derived from plant material for smoking or consumption as edibles, without controls for dose, THC or CBD content, or oversight by health care professionals. Even in the rare cases when “medical marijuana” products claim to contain only CBD, there are no standards or protections in place to assess concentration, purity, safety or effectiveness.
- ❖ GW hopes to begin Epidiolex clinical trials this year, and may pursue other FDA pre-approval pathways, including some that could greatly accelerate research and increase medical access to Epidiolex, possibly to include treatments for other seizure disorders (e.g., Lennox-Gastaut syndrome).
- ❖ University of Iowa Hospitals and Clinics Director of Pediatric Epilepsy in the Division of Pediatric Neurology—Dr. Joshi Charuta, MBBS—has already applied on behalf of two Iowa families for access to Epidiolex via the IND program. At least two Iowa health care centers are considering applying to participate in expanded clinical trials, which could further increase patient access to this experimental drug.

In summary, ODCP is encouraged by recent advancements in isolating cannabis-based drugs for FDA-authorized testing of what could become safe and effective medicines, without compounding the detrimental effects of marijuana. New standardized research, coupled with the fact that two other cannabis-based medicines are already FDA-approved and available in pill form by prescription (Marinol and Cesamet), demonstrates progress on this front. ODCP remains hopeful this type of research will continue with urgency, to help those in need.

Contact information for patients, families, physicians, colleagues and other interested Iowans:

- GW’s IND program: Patients should ask their physician to write directly to GW’s in-house physician, Dr. Eltayb at info@gwpharm.com.
- Dravet Syndrome Foundation: 203-880-9456 or info@dravetfoundation.org.
- FDA Office of Health and Constituent Affairs (Richard Klein or Deborah Miller are available to help families understand and navigate FDA procedures): 301-796-8460 or ohca@fda.hhs.gov.
- Dr. Joshi Charuta, University of Iowa Hospitals and Clinics: (319) 356-1851.